REMARKS

The Office Action dated November 25, 2003 has been carefully considered. Claims 12, 17, 33, 36 and 39 have been amended. Claims 12, 14, 15, 17, 19, 20 and 33-40 are in this application.

The previously presented claims were rejected under 35 U.S.C. § 101 as directed to non-statutory matter.

The Examiner indicated that the claims do not produce a useful concrete and tangible result.

Applicant has amended the claims to define the invention as directed to a method of treating a postnatal or premature baby for accelerating or decelerating the cortical alpha rhythms. Support for this amendment is found throughout the specification and in particular on page 7, lines 11-36.

Applicants note that the Federal Circuit has stated, "[t]o violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 USPQ2d 1401, 1412 (Fed. Cir. 1992) (emphasis added). See also *E.I. du Pont De Nemours and Co. v. Berkley and Co.*, 620 F.2d 247, 1260 n. 17, 205 USPQ 1, 10 n. (8th Cir. 1980) (A small degree of utility is sufficient . . . . The claimed invention must only be capable of performing some beneficial function . . . . An invention does not lack utility merely because the particular embodiment disclosed in the patent lacks perfection or performs crudely . . . . A commercially successful product is not required . . . . Nor is it essential that the invention accomplish all its intended functions . . . or operate under all conditions . . . partial success being sufficient to demonstrate patentable utility . . . . In short, the defense is only partially successful in achieving a useful result, a rejection of the claimed invention as a whole based on a lack of utility is not appropriate. See *In re Brana*, 51 F.3d 1389, 177 USPQ 396 (CCPA), *reh'g denied*, 480 F.2d 879 (CCPA 1973); In re Marzocci, 439 F.2d 220, 169 USPQ 367 (CCPA 1971).

As a general matter, evidence of pharmacological or biological activity of a compound will be relevant to an asserted therapeutic use if there is a reasonable correlation between the activity in question and the asserted utility. *Cross v Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed.

Cir. 1985); *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *Nelson v. Bowler*, 626 F.2d 853, 206 USPQ 881 (CCPA 1980). An applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of a compound or composition, arguments or reasoning, documentary evidence (e.g., articles in scientific journals), or any combination thereof. The applicant does not have to prove that a correlation exists between a particular activity and an asserted therapeutic use of a compound as a matter of statistical certainty, nor does he or she have to provide actual evidence of success in treating humans where such a utility is asserted. Instead, as the courts have repeatedly held, all that is required is a reasonable correlation between the activity and the asserted use. *Id.* at 857.

As noted in the Declaration of Brent Logan, Ph.D. submitted herewith, the invention defined by the present claims is capable of achieving a useful result.

Applicant submits that the treatment method of the present invention can be practiced without undue experimentation by applying a pattern of sonic variations in alpha rhythm in which a tempo at which each subsequent sequence of time is represented is increased or decreased tempo to achieve accelerating or decelerating cortical alpha rhythms. As described on page 7, lines 23-26, the duration or effect is dependent on length of Applicant user psychodynamics and environmental features. As set forth in the present invention, the elevation or decreasing alpha rhythm can be measured by electroencephalography, MRI, PET and standard instruments for detecting and recording brain waves and can track the magnitude and transmission speed of a neural response. Accordingly, undue experimentation is not required in the method or system of the present invention.

As the claimed invention is directed towards statutory subject matter, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. § 101.

Claims 33-35 were rejected under double patent in view of U.S. patent No. 6,494,719 in view of U.S. Patent No. 6,443,977. Applicant hereby submits a terminal disclaimer disclaiming the terminal portion of a patent granted on the present application which would extend beyond the dates of the '719 patent.

In view of the foregoing, Applicants submit that all pending claims are in condition for allowance and request that all claims be allowed. The Examiner is invited to contact the

undersigned should he believe that this would expedite prosecution of this application. It is believed that no fee is required. The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 13-2165.

Respectfully submitted,

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